Puget Sound Blood Center
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December 9, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

'99 DEC 17 A9:50

Re: **Docket 98N-0581**
Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents.

To Whom It May Concern:

Please accept the following comments relating to Docket 98N-0581, "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents":

610.40 (a)
Although many blood centers routinely test autologous units for infectious disease markers, to require that this be done is unnecessary, expensive, and adds nothing to transfusion safety, particularly since these units will be released for transfusion even if the testing is positive. Since the concern is that the units might be unintentionally crossed over to allogeneic use, the critical requirement should be that the units appear so different from allogeneic units that this is not likely. FDA already requires that autologous units look very different from allogeneic units. If need be, additional differences could be achieved by requiring that untested units be clearly labeled with prominently displayed statements such as "Biohazard" (as are the tested and positive units) or "Untested for Infectious Diseases".

It is desirable to maintain the exemption from testing each donation of dedicated apheresis donors. The current requirement that these donors be tested only once at the beginning of a 30-day period has been used successfully for 10-15 years and is very workable. Patients receiving such donations are often in dire clinical straits and unable to wait the 12-24 hours now required for completion of testing. To require completion of testing for each donation, which may occur as often as daily, serves only to delay the delivery of the component to the patient and to increase the paperwork for those patients who simply cannot wait.

610.40 (c)
The requirement that blood establishments perform supplemental testing on donors found to be repeatedly reactive by screening tests would not improve the safety of the blood supply. The fact that most blood establishments do such testing does not imply that such activity should be mandated. The FDA's concern should be only that the donor is deferred and the products discarded or properly labeled. Whether additional testing (Western blots, ALT, NAT, additional liver function tests, liver biopsy) is performed by the blood establishment or by the patient's health care provider or not at all are medical care issues and not ones that should be regulated by the FDA.

To require that supplemental testing be performed for autologous donors is inappropriate. Medicare rules consider such reflex testing fraudulent. These patients are already under the

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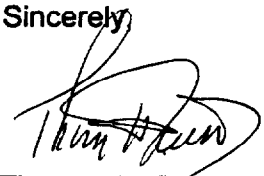
care of a physician who has ordered the collection of autologous blood as a medical procedure. As with any clinical laboratory test, the acceptable way for the blood establishment to deal with a positive screening test is to notify the patient's physician. The physician is the authority appropriately situated to determine if supplemental testing is medically indicated.

610.40 (f)
The requirement that components collected from a donor who tests repeatedly reactive in a screening test not be used for transfusion should be modified to allow such transfusion if determined medically necessary by a physician. There are instances where HLA matched/family platelet donors are the only donors capable of supporting the patient or where the marrow donor must continue to support the transplant recipient. In dire medical need, it may be appropriate to use such donors even if certain screening tests are positive. Allowance for these exceptions should be made.

610.41 (a)
This requirement should be amended to say "Donors who test repeatedly reactive for HTLV, types I and II or anti-HBc on only one occasion, unless further testing under 610.40 (c) **is positive**".

Sincerely,



Thomas H. Price, MD
Medical Director

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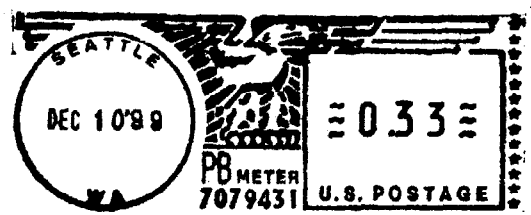

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